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- AUTHORITY: 21 U.S.C. 111, 114, 114a, and 134a–134h; 7 CFR 2.22, 2.80, and 371.4.

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§ 54.1 Definitions.

Accredited veterinarian. A veterinarian approved by the Administrator in accordance with part 161 of this chapter to perform functions specified in subchapters B, C, and D of this chapter.

Administrator. The Administrator of the Animal and Plant Health Inspection Service or any employee of the United States Department of Agriculture authorized to act for the Administrator.

Animal. A sheep or goat.

Animal and Plant Health Inspection Service (APHIS). The Animal and Plant Health Inspection Service of the United States Department of Agriculture.

APHIS representative. An individual employed by APHIS in animal health activities who is authorized by the Administrator to perform the function involved.

Approved laboratory. A laboratory approved by the Administrator in accordance with § 54.11 to conduct one or more scrapie tests, or genotype tests, on one or more tissues.

Approved test. A test for the diagnosis of scrapie approved by the Administrator for use in the scrapie eradication or certification program in accordance with § 54.10.

Area veterinarian in charge. The veterinary official of APHIS who is assigned by the Administrator to supervise and perform the official animal health work of APHIS in the State concerned.

Breed association and registries. Organizations listed in § 151.9 of this chapter that maintain the permanent records of ancestry or pedigrees of animals (including the animal's sire and dam), individual identification of animals, and ownership of animals.

Certificate. An official document issued in accordance with § 79.5 of this chapter by an APHIS representative, State representative, or accredited veterinarian at the point of origin of an interstate movement of animals.

Commingle, commingled, commingling. Animals grouped together and having physical contact with each other, including contact through a fence, but not limited contacts. Commingling also includes sharing the same section in a transportation unit where there is physical contact.

Designated scrapie epidemiologist. An epidemiologist who has demonstrated the knowledge and ability to perform the functions required and who has been selected by the State animal health official and the area veterinarian in charge. The regional epidemiologist and the APHIS National Scrapie Program Coordinator must concur in the selection and appointment of the designated scrapie epidemiologist. The designated scrapie epidemiologist must satisfactorily complete training designated by APHIS.

Destroyed. (1) Euthanized by means other than slaughter, and the carcass disposed of, by means authorized by the Administrator; or

(2) In the case of exposed or high-risk animals that are not known to be infected, either euthanized or disposed of by slaughter; or

(3) Moved to a quarantined research facility if the movement has been approved by the Administrator.

Electronic implant. Any radio frequency identification implant device approved for use in the scrapie program

by the Administrator. The Administrator will approve an electronic implant after determining that it is tamper resistant, not harmful to the animal, and readable by equipment available to APHIS and State representatives.

Exposed animal. (1) Any animal that has been in the same flock at the same time as a scrapie-positive female animal, excluding limited contacts; or

(2) Any animal born in a flock after a scrapie-positive animal was born into that flock or lambed in that flock, if born before that flock completes the requirements of a flock plan; or

(3) Any animal that was commingled with a scrapie-positive female animal during or up to 30 days after she lambed, kidded, or aborted, or while a visible vaginal discharge was present, or that was commingled with any other scrapie-positive female animal for 24 hours or more, including during activities such as shows and sales or while in marketing channels; or

(4) Any animal in a noncompliant flock.

Exposed flock. Any flock in which a scrapie-positive animal was born or lambed. Any flock that currently contains a female high-risk, exposed, or suspect animal, or that once contained a female high-risk, exposed, or suspect animal that lambed in the flock and from which tissues were not submitted for official testing and found negative. A flock that has completed a post-exposure management and monitoring plan following the exposure will no longer be an exposed flock.

Flock. All animals that are maintained on a single premises and all animals under common ownership or supervision on two or more premises with animal interchange between the premises. Changes in ownership of part or all of a flock do not change the identity of the flock or the regulatory requirements applicable to the flock. Animals maintained temporarily on a premises for activities such as shows and sales or while in marketing channels are not a flock. More than one flock may be maintained on a single premises if:

(1) The flocks are enrolled as separate flocks in the SFCP; or

(2) A State or APHIS representative determines, based upon examination of flock records, that:

(i) There is no interchange of animals between the flocks;

(ii) The flocks never commingle and are kept at least 30 feet apart at all times or are separated by a solid wall through, over, or under which fluids cannot pass and through which contact cannot occur;

(iii) The flocks have separate flock records and identification;

(iv) The flocks have separate lambing facilities, including buildings and pastures, and a pasture or building used for lambing by one flock is not used by the other flock at any time; and

(v) The flocks do not share equipment without cleaning and disinfection in accordance with § 54.7(e). Additional guidance on acceptable means of cleaning and disinfection is also available in the Scrapie Flock Certification Program standards and the Scrapie Eradication Uniform Methods and Rules.

Flock of origin. The flock in which an animal most recently resided in which it either was born, gave birth, or was used for breeding purposes. The determination of an animal's flock of origin may be based either on the physical presence of the animal in the flock, the presence of official identification on the animal traceable to the flock, the presence of other identification on the animal that is listed on the bill of sale, or other evidence, such as registry records.

Flock plan. A written flock management agreement signed by the owner of a flock, the accredited veterinarian, if one is employed by the owner, and a State or APHIS representative in which each participant agrees to undertake actions specified in the flock plan to control the spread of scrapie from, and eradicate scrapie in, an infected flock or source flock or to reduce the risk of the occurrence of scrapie in a flock that contains a high-risk or an exposed animal. As part of a flock plan, the flock owner must provide the facilities and personnel needed to carry out the requirements of the flock plan. The flock plan must include the requirements in § 54.8(a) through (f).

Flock sire. A sexually intact male animal that has ever been used for breeding in a flock.

High-risk animal. A sexually intact animal, excluding male sheep that have tested RR at codon 171 and AA at codon 136 using an official genotype test, that is:

(1) The progeny of a scrapie-positive dam; or

(2) Born in the same flock during the same lambing season as progeny of a scrapie-positive dam, unless the progeny of the scrapie-positive dam are from separate contemporary lambing groups; or

(3) Born in the same flock during the same lambing season that a scrapie-positive animal was born, or during any subsequent lambing season, if born before that flock completes the requirements of a flock plan; or

(4) An exposed female sheep that has not tested QR, HR, or RR at codon 171 using an official genotype test.

Infected flock. The flock of origin of a female animal that a State or APHIS representative has determined to be a scrapie-positive animal; or any flock in which a State or APHIS representative has determined that a scrapie-positive female animal has resided unless an epidemiologic investigation conducted by a State or APHIS representative shows that the animal did not lamb or abort in the flock. A flock will no longer be considered an infected flock after it has completed the requirements of a flock plan.

Limited contacts. Incidental contacts between animals from different flocks off the flock's premises such as at fairs, shows, exhibitions and sales; between ewes being inseminated, flushed, or implanted; or between rams at ram test or collection stations. Embryo transfer and artificial insemination equipment and surgical tools must be sterilized between animals for these contacts to be considered limited contacts. Limited contacts do not include any contact, incidental or otherwise, with animals in the same flock or with a female animal during or up to 30 days after she lambed, kidded or aborted or when there is any visible vaginal discharge. Limited contacts do not include any activity where uninhibited contact occurs, such as sharing an en-

closure, sharing a section of a transport vehicle, or residing in other flocks for breeding or other purposes. Examples of limited contacts may be found in the Scrapie Flock Certification Program standards.

Live-animal screening test. Any test for the diagnosis of scrapie in a live animal that is approved by the Administrator as usually reliable but not definitive for diagnosing scrapie, and that is conducted in a laboratory approved by the Administrator.¹

Mortgage. Any mortgage, lien, or other security or interest held by any person other than the one claiming indemnity.

National Scrapie Database. A database designated by the Administrator in which APHIS and State animal health agencies cooperatively enter data concerning scrapie outbreaks, flocks and premises affected by scrapie, individual animal identification and premises identification data, and other data to support the Scrapie Eradication Program and the Scrapie Flock Certification Program.

National Veterinary Services Laboratories (NVSL). The National Veterinary Services Laboratories, APHIS, U.S. Department of Agriculture, or an NVSL cooperating or contract laboratory.

¹The names and addresses of laboratories approved by the Administrator to conduct live-animal screening tests will be published in the Notices Section of the FEDERAL REGISTER. A list of approved laboratories is also available upon request from the Animal and Plant Health Inspection Service, Veterinary Services, National Animal Health Programs Staff, 4700 River Road Unit 43, Riverdale, MD 20737-1235. State, Federal, and university laboratories will be approved by the Administrator when he or she determines that the laboratory: (a) Employs personnel trained by the National Veterinary Services Laboratories assigned to supervise the testing; (b) follows standard test protocols; (c) meets check test proficiency requirements; and (d) will report all test results to State and Federal animal health officials. Before the Administrator may withdraw approval of any laboratory for failure to meet any of these conditions, the Administrator must give written notice of the proposed withdrawal to the director of the laboratory and must give the director an opportunity to respond. If there are conflicts as to any material fact, a hearing will be held to resolve the conflicts.

Noncompliant flock. (1) Any source or infected flock whose owner declines to enter into a flock plan or post-exposure management and monitoring plan agreement within 30 days of being so designated, or whose owner is not in compliance with either agreement;

(2) Any exposed flock whose owner fails to make animals available for testing within 60 days of notification, or as mutually agreed, or whose owner fails to submit required postmortem samples;

(3) Any flock whose owner has misrepresented, or who employs a person who has misrepresented, the scrapie status of an animal or any other information on a certificate, permit, owner statement, or other official document within the last 5 years; or

(4) Any flock whose owner or manager has moved, or who employs a person who has moved, an animal in violation of this chapter within the last 5 years.

Official genotype test. Any test to determine the genotype of a live or dead animal that is conducted at either an approved laboratory or at the National Veterinary Services Laboratories, when the animal is officially identified and the samples used for the test are collected and shipped to the laboratory by either an accredited veterinarian or a State or APHIS representative

Official test. Any test for the diagnosis of scrapie in a live or dead animal that is approved by the Administrator for that use and conducted either at an approved laboratory or at the National Veterinary Services Laboratories.

Owner. A person, partnership, company, corporation, or any other legal entity who has legal or rightful title to animals, whether or not they are subject to a mortgage.

Post-exposure management and monitoring plan. A written agreement signed by the owner of a flock, any accredited veterinarian employed by the owner, and a State or APHIS representative in which each participant agrees to undertake actions specified in the agreement to monitor for the occurrence of scrapie in the flock for at least 5 years after the last high-risk or scrapie-positive animal is removed from the flock or after the last exposure of the flock to a scrapie-positive animal, unless

otherwise specified by a State or APHIS representative. As part of a post-exposure management and monitoring plan, the flock owner must provide the facilities and personnel needed to carry out the requirements of the plan. The plan must include the requirements in § 54.8.

Scrapie control pilot project. A pilot project authorized by the Administrator in writing, designed to test or improve program procedures or to facilitate research, in order to control and eradicate scrapie. In addition to APHIS, participants may include State animal health agencies, flock owners, and other parties as necessary.

Scrapie Eradication Program. The cooperative State-Federal program administered by APHIS and Consistent States to control and eradicate scrapie.

Scrapie Eradication Uniform Methods and Rules (UM&R). Cooperative procedures and standards adopted by APHIS and Consistent States for controlling and eradicating scrapie. The UM&R will be reviewed at least annually by representatives of the livestock industry and appropriate State and Federal agencies and the public and will be revised, and published as needed by APHIS.

Scrapie Flock Certification Program (SFCP). The cooperative Federal-State-industry voluntary program for the control of scrapie conducted in accordance with this subpart.

Scrapie Flock Certification Program standards. Cooperative procedures and standards adopted by APHIS and State scrapie certification boards for reducing the incidence and controlling the spread of scrapie through flock certification.²

Scrapie-positive animal. An animal for which a diagnosis of scrapie has been made by the National Veterinary Services Laboratories or another laboratory authorized by the Administrator to conduct scrapie tests in accordance with this part, through:

²Individual copies of the Scrapie Flock Certification Program standards may be obtained on the World Wide Web at URL <http://www.aphis.usda.gov/vs/scrapie>, or from the Animal and Plant Health Inspection Service, National Animal Health Programs Staff, 4700 River Road Unit 43, Riverdale, MD 20737-1235.

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(1) Histopathological examination of central nervous system (CNS) tissues from the animal for characteristic microscopic lesions of scrapie;

(2) The use of proteinase-resistant protein analysis methods including but not limited to immunohistochemistry and/or western blotting on CNS and/or peripheral tissue samples from a live or a dead animal for which a given method has been approved by the Administrator for use on that tissue;

(3) Bioassay;

(4) Scrapie associated fibrils (SAF) detected by electron microscopy; or

(5) Any other test method approved by the Administrator in accordance with § 54.10.³

Separate contemporary lambing groups. To be a separate contemporary lambing group, the group must be maintained separately such that the animals cannot come into physical contact with other lambs, kids, ewes or does or birth fluids or placenta from other ewes or does. This separate maintenance must preclude contact through a fence, during lambing and for 60 days following the date the last lamb or kid is born in a lambing season, and must preclude using the same lambing facility as other ewes or does, unless the lambing facility is cleaned and disinfected under supervision by an

APHIS representative, State representative, or an accredited veterinarian between lambings in accordance with § 54.7(e). Additional guidance on acceptable means of cleaning and disinfection is also available in the Scrapie Flock Certification Program standards and the Scrapie Eradication Uniform Methods and Rules. The flock owner must maintain adequate records to document which animals were maintained in each contemporary lambing group and to document when cleaning and disinfection was performed and who supervised it.

Slaughter channels. Animals in slaughter channels include any animal that is sold, transferred, or moved either directly to a slaughter facility, to an individual for custom slaughter, or for feeding for the express purpose of improving the animals' condition for movement to slaughter. Any sexually intact animal that is commingled with breeding animals or that has been bred is not in slaughter channels. When selling animals for slaughter, owners should note on the bill of sale that the animals are sold only for slaughter.

Source flock. A flock in which a State or APHIS representative has determined that at least one animal was born that was diagnosed as a scrapie-positive animal at an age of 72 months or less. The determination that an animal was born in a flock will be based on such information as the presence of official identification on the animal traceable to the flock, the presence of other identification on the animal that is listed on the bill of sale, or other evidence, such as registry records, to show that a scrapie-positive animal was born in the flock, combined with the absence of records indicating that the animal was purchased from outside and added to the flock. If DNA from the animal was previously collected by an accredited veterinarian and stored at an approved genotyping laboratory, or if DNA collection and storage are required for breed registration and the breed registration has appropriate safeguards in place to ensure the integrity of the banking process, the owner may request verification of the animal's identity based on DNA comparison if adequate records and identification have been maintained by the owner and

³The names and addresses of laboratories approved by the Administrator to conduct tests are published in the Notices Section of the FEDERAL REGISTER. A list of approved laboratories is also available upon request from the Animal and Plant Health Inspection Service, Veterinary Services, National Animal Health Programs Staff, 4700 River Road Unit 43, Riverdale, MD 20737-1235. State, Federal, and university laboratories will be approved by the Administrator when he or she determines that the laboratory: (a) Employs personnel trained by the National Veterinary Services Laboratories assigned to supervise the testing; (b) follows standard test protocols; (c) meets check test proficiency requirements; and (d) will report all test results to State and Federal animal health officials. Before the Administrator may withdraw approval of any laboratory for failure to meet any of these conditions, the Administrator must give written notice of the proposed withdrawal to the director of the laboratory and must give the director an opportunity to respond. If there are conflicts as to any material fact, a hearing will be held to resolve the conflict.

the repository to show that the archived DNA is that of the animal that has been traced to the flock. The owner will be responsible for all costs for the DNA comparison. A flock will no longer be a source flock after it has completed the requirements of a flock plan.

State. Each of the 50 States, the District of Columbia, the Northern Mariana Islands, Puerto Rico, and all territories or possessions of the United States.

State representative. An individual employed in animal health activities by a State or a political subdivision of a State and who is authorized by the State or political subdivision to perform the function involved.

Suspect animal. An animal will be designated a suspect animal in accordance with § 79.4 of this chapter if it is:

(1) A sheep or goat that exhibits any of the following possible signs of scrapie and that has been determined to be suspicious for scrapie by an accredited veterinarian or a State or APHIS representative: Weight loss despite retention of appetite; behavioral abnormalities; pruritus (itching); wool pulling; biting at legs or side; lip smacking; motor abnormalities such as incoordination, high stepping gait of forelimbs, bunny hop movement of rear legs, or swaying of back end; increased sensitivity to noise and sudden movement; tremor, "star gazing," head pressing, recumbency, or other signs of neurological disease or chronic wasting.

(2) A sheep or goat that has tested positive for scrapie or for the proteinase resistant protein associated with scrapie on a live-animal screening test or any other test, unless the animal is designated a scrapie-positive animal.

(3) A sheep or goat that has tested inconclusive or suggestive on an official test for scrapie.

Unofficial test. Any test for the diagnosis of scrapie or for the detection of the proteinase resistant protein associated with scrapie in a live or dead animal that either has not been approved by the Administrator or that was not conducted at an approved laboratory or at the National Veterinary Services Laboratories.

§ 54.2 Cooperative agreements and memoranda of understanding with States.

APHIS will execute cooperative agreements and/or memoranda of understanding with the animal health agency of any State in order to cooperatively administer the Scrapie Eradication Program and the Scrapie Flock Certification Program within that State. These agreements will describe the respective roles of APHIS and State personnel in implementing the Scrapie Eradication Program and the Scrapie Flock Certification Program. Each agreement may specify the financial, material, and personnel resources to be committed to these programs and other scrapie control measures by APHIS and the State; assign specific activities related to the control of scrapie within a State to APHIS or State personnel; establish schedules for APHIS representatives or State representatives to visit flocks; establish procedures for maintaining and sharing program records specified in this part, and specify other responsibilities of State representatives and APHIS representatives in support of the Scrapie Eradication Program and the Scrapie Flock Certification Program.

(Approved by the Office of Management and Budget under control number 0579-0101)

Subpart A—Scrapie Indemnification Program

§ 54.3 Animals eligible for indemnity payments.

(a) Indemnity may be paid for an animal only after the owner of the animal has applied for indemnification and been approved in accordance with § 54.4. Indemnity may be paid only for the following:

- (1) Destruction of high-risk animals;
- (2) Destruction of animals based on an epidemiologic investigation, when the Administrator determines that the destruction of these animals will contribute to the eradication of scrapie;
- (3) Destruction of live scrapie-positive animals;
- (4) Destruction of animals that test positive on a live-animal screening test; and